IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

ALOPEXX, INC.,
186 Brook Parkway #1068
Cambridge, MA 02138

Plaintiff,

v.

XENOTHERA,
21 Rue La Noue Bras de Fer
44200 Nantes, Frances

Defendant.

Civil Case No. 22-11081

COMPLAINT

Plaintiff Alopexx, Inc. ("Alopexx") brings this action against Defendant Xenothera ("Xenothera") and alleges as follows:

INTRODUCTION

1. Give them an inch and they will take a mile. This case, unfortunately, is proof positive of that age-old expression.

2. In 2018, Alopexx provided Xenothera—free of charge—with a small amount of Alopexx's proprietary anti-infective vaccine, AV0328, to conduct a single experiment. Alopexx and Xenothera expressly agreed in a Material Transfer Agreement ("MTA") that Xenothera had no right to use the vaccine for anything other than the single, limited experiment and that Xenothera could not take any action that may affect Alopexx's rights without Alopexx's express approval.

3. Without a license or Alopexx's authorization, Xenothera improperly leveraged Alopexx's vaccine to develop a product candidate—a polyclonal antibody called XAB05—that

would compete with Alopexx's own proprietary product candidate—a monoclonal antibody called F598. Xenothera's product candidate would not exist without Alopexx's vaccine, which Alopexx provided free of charge for a one-time, narrow research project. And Xenothera cannot develop its product candidate any further without a license to use Alopexx's vaccine, which Xenothera does not have.

4. Now, after proclaiming that it is "preparing" to "ramp-up" its product candidate, Xenothera insists for the first time that Alopexx is *legally obligated* to provide Xenothera with a license to use Alopexx's vaccine. In other words, after paying nothing for a small amount of vaccine delivered once nearly four years ago, Xenothera now claims it has a legal right to use Alopexx's vaccine forever—despite unambiguous contractual provisions stating the opposite.

5. Alopexx is a clinical stage biotechnology company developing novel immune therapeutics with the goal of reducing reliance on antibiotics. Alopexx has two proprietary, clinical therapeutic candidates: a chemically synthesized vaccine ("AV0328") and a fully human monoclonal antibody ("F598"). In development since 2006, F598 is being studied for initial use in preventing hospital-acquired infections in intensive care patients. Alopexx has completed first-in-man and pilot clinical studies and has planned Phase II proof-of-concept trials for both the vaccine and the antibody. On the strength of these candidate therapeutics, Alopexx announced earlier this year that it intends to raise funds through an initial public offering ("IPO").

6. Just months after announcing its planned IPO, Alopexx received a baseless license demand from Xenothera. Citing the narrow and short-term 2018 MTA, Xenothera has asserted entitlement to license Alopexx's AV0328 vaccine, which Xenothera requires to study and produce XAB05, Xenothera's own polyclonal antibody product.

7. Like Alopexx's F598, Xenothera's XAB05 is an antibody designed for use in treating and preventing microbial infections. The target of both of those products is the same, Poly-N-acetyl glucosamine ("PNAG")—a broadly expressed component of the microbial surface identified by Dr. Gerald Pier, a co-founder of Alopexx. However, unlike F598, production of XAB05 requires the immunization of animals with a relevant vaccine to induce development of sera containing those antibodies. In this case, the relevant vaccine is Alopexx's proprietary AV0328 vaccine. Xenothera apparently plans to study XAB05 for many of the same indications for which Alopexx has or may evaluate F598, putting the product candidates in competition with one another. Thus, Xenothera seeks to force Alopexx to license proprietary technology to its competitor in order to undermine Alopexx's own nascent business. Neither the law nor the narrow MTA require such self-destructive behavior. Xenothera's license demand is entirely without merit.

8. While frivolous, Xenothera's license demand has called into doubt Alopexx's control over its valuable intellectual property and has wrongly suggested to prospective Alopexx investors that there may be a viable alternative to F598. As a result, Xenothera's demand is causing and will continue to cause substantial harm to Alopexx as long as it remains unresolved. Alopexx thus seeks (1) a declaratory judgment that Xenothera—despite its baseless claims to the contrary—has no right or license to use Alopexx's proprietary vaccine technology without permission from Alopexx; and (2) damages for Xenothera's serious breaches of the MTA.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. § 1332 because the parties have complete diversity of citizenship and the amount in controversy exceeds the jurisdictional amount.

10. This Court has authority to grant the requested declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

11. This Court has personal jurisdiction over Defendant Xenothera because Xenothera transacted business from which this action arises within this District, Xenothera has significant contacts with this District related to this action, and Xenothera agreed in the MTA that "any action arising out of or related to this Agreement may be brought in the Massachusetts state courts or the US federal courts sitting in Boston, Massachusetts" and "the parties hereby submit to the in personum jurisdictions of each such courts for such purposes."

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

PARTIES

13. Plaintiff Alopexx is a U.S. corporation organized and existing under the laws of Delaware and headquartered in Massachusetts. Its principal place of business is 186 Alewife Brook Pkwy #1068, Cambridge, Massachusetts 02138.

14. Defendant Xenothera is, on information and belief, a corporation organized and existing under the laws of France, having its principal place of business at 21 Rue La Noue Bras de Fer, 44200 Nantes, France.

FACTUAL BACKGROUND

A. Alopexx's Pioneering Immune Therapies

15. Bacterial infections are a major cause of death and disability worldwide. Since the 1940s, antibiotics have been widely used to treat and prevent bacterial infections. Increasingly, though, antibiotic-resistant infections have rendered certain medicines ineffectual, threatening millions of people each year.

16. Alopexx develops novel immune therapies for bacterial, fungal, and parasitic infections. Alopexx's work and mission stem from the efforts of one of its founders, Gerald Pier,

Ph.D. Dr. Pier is a Professor of Medicine in the fields of microbiology and immunology at Harvard Medical School and Brigham and Women's Hospital.

17. Dr. Pier's laboratory at Harvard Medical School identified, developed, and advanced the study of PNAG, a critical component of the surface of bacteria and fungi causing serious infections. Dr. Pier's laboratory recognized that PNAG is an ideal target for immune therapeutics and that developing therapies to target PNAG may avoid or reduce the need for antibiotics.

18. Dr. Pier and Dr. Daniel Vlock co-founded Alopexx in 2006.

19. Dr. Pier currently serves as Alopexx's Chief Scientific Officer and Chair of its Scientific Advisory Board. Dr. Vlock currently serves as Alopexx's Chief Executive Officer.

20. Initially, Drs. Pier and Vlock founded Alopexx to develop F598, a human monoclonal antibody that targets PNAG on the surface of microbes and utilizes the host's immune response to kill those pathogens. F598 can target a number of bacterial, fungal, and parasitic infections, providing immediate and near-term protection against infection and as well as treating active infections. Alopexx plans to seek initial regulatory approval for F598 to be used to prevent hospital-acquired infections in intensive care unit patients.

21. Drs. Pier and Vlock also developed AV0328, a synthetic PNAG vaccine candidate. AV0328 has been found to induce antibodies capable of killing a wide range of pathogens by targeting PNAG on the surface of microbes.

22. Pursuant to a license agreement with Brigham and Women's Hospital, Alopexx has an exclusive, worldwide, royalty-bearing license relating to development, utilization, and commercialization of all therapeutics and diagnostics targeting PNAG. Separate licensing agreements with Brigham and Women's Hospital provide Alopexx with an exclusive, royalty-

bearing license to certain U.S. and foreign patents related to the vaccine and the antibody. Brigham and Women's Hospital has retained small amounts of AV0328 and F598, which it may provide to organizations for non-commercial, research purposes.

23. Approximately $140 million has been invested to date in the development of the F598 monoclonal antibody and the AV0328 vaccine.

24. Alopexx estimates the potential initial market opportunity for F598 and AV0328 exceeds $4 billion.

25. Alopexx has completed a series of studies on its proprietary vaccine and antibody, demonstrating that both are safe and capable of combating numerous pathogens.

26. Alopexx has developed and planned Phase II proof-of-concept trials for both the antibody and the vaccine. Alopexx believes that its planned clinical development will ultimately result in regulatory approvals that will put its vaccine and antibody on the path to addressing the significant and growing need for non-antibiotic therapies.

27. In March 2022, Alopexx announced plans to raise funds on the public markets to fund the planned Phase II trials and other critical research activities.

B. 2018 Material Transfer Agreement

28. In April 2018, Xenothera sought permission from Alopexx to conduct a short-term experiment using Alopexx's vaccine to determine whether immunization of three genetically modified pigs could be used to create antisera against certain PNAG-expressing microbes. Hyperimmunization of animals is a well-established method to produce antisera for diagnostic and therapeutic uses.

29. Although Alopexx's own F598 monoclonal antibody may have similar utility to an antisera created through immunization, Alopexx entertained the idea of a preliminary collaboration

with Xenothera because antisera induced by vaccination might have utility distinct from a monoclonal antibody.

30. Following discussions about the limited nature of Xenothera's planned research, the parties entered into the MTA on May 30, 2018. A true and correct copy of the MTA is attached to this Complaint.

31. Under the MTA, Alopexx agreed to provide Xenothera with enough AV0328 vaccine to inoculate three animals. MTA ¶ 1.1. The vaccine was provided "free of charge." MTA ¶¶ 1.1, 2.

32. Alopexx also granted to Xenothera "a ***temporary***, nonexclusive right to use [the vaccine] ***solely*** as expressly provided in this Agreement." MTA ¶ 1.1 (emphases added).

33. The MTA expressly provided that "XENOTHERA shall not be authorized to use the [AV0328 vaccine] after the expiry date of this Agreement or for any purposes other than the PURPOSE, without ALOPEXX further, prior and written consent." MTA¶ 1.2.

34. The sole "PURPOSE" set out in the Agreement is that "Xenothera will use the [AV0328 vaccine] in order to obtain antibodies from animals that will be hyper-immunized against the [AV0328 vaccine]." MTA ¶ 1.3.

35. The MTA provided for no additional research beyond the inoculation of three animals with the AV0328 vaccine. "According to the results obtained," the MTA stated, Alopexx and Xenothera would jointly "decide whether to go on with further immunizations of the same animals, or to launch a new trial." MTA ¶ 1.4. Neither Alopexx nor Xenothera committed to continued collaboration of any kind regarding the AV0328 vaccine.

36. The MTA conveyed only a limited, temporary, and nonexclusive right to use AV0328. The MTA did not grant any license or other rights to use AV0328 for anything beyond

the narrow purpose set out in the MTA. As stated in the MTA, "[t]he Parties . . . agree[d] that the right to use the [AV0328 vaccine], as granted under this Agreement, ***may not, under any circumstances, be construed as expressly or implicitly providing XENOTHERA with any ownership right or title, or option or license***, whatsoever over the [AV0328 vaccine]." MTA ¶ 4.2 (emphasis added). Moreover, the MTA provided that "***No license shall be implicitly granted*** as a result of ALOPEXX providing the [AV0328 vaccine] to XENOTHERA." MTA ¶ 5.3 (emphasis added).

37. Additionally, the MTA precluded Xenothera from "conduct[ing] operations or transformations that may affect the rights of ALOPEXX, without the prior written consent of ALOPEXX." MTA ¶ 4.3.

38. The Agreement was to "remain in force for one (1) year from the last date of signature." MTA ¶ 9.1. While the MTA could be extended by written mutual agreement of the parties, no such agreement to extend was ever reached.

39. The MTA provides that the "Party breaching or threatening to breach this Agreement shall, in addition to all other damages and costs, be liable for payment to the Party enforcing its rights hereunder its reasonable attorney fees." MTA ¶ 14.

C. Xenothera's 2019 Requests to License the AV0328 Vaccine

40. In spring 2019, following the experiment contemplated by the MTA, and recognizing that it lacked rights to do anything further with Alopexx's proprietary vaccine, Xenothera wrote to Alopexx seeking to explore the possibility of a licensing agreement for AV0328. As its CEO wrote at the time, Xenothera was interested in negotiating "an official right to use your vaccine in order to move forward, and define financial compensation if the product happens to be successful."

41. Xenothera shared with Alopexx the results of the experiment conducted pursuant to the MTA. While the parties discussed the results of Xenothera's one-time experiment, there was no discussion—apart from the email referenced in Paragraph 41—of Xenothera obtaining a license to use AV0328 or any other Alopexx technology in the future. Nor were there any discussions of continued experimentation by Xenothera related to Alopexx's AV0328 vaccine or antisera induced through use of the vaccine.

D. Xenothera's 2021 Requests to License the AV0328 Vaccine

42. For almost two years, Alopexx heard nothing from Xenothera. Then, in January 2021, Xenothera contacted Alopexx regarding additional work Xenothera had performed with antisera derived from the 2018 limited experiment.

43. In these 2021 discussions, Xenothera referred to the antisera derived from Alopexx's AV0328 vaccine as XAB05. Xenothera sought a license to Alopexx's AV0328 vaccine in order to continue to produce and study XAB05.

44. Xenothera also described for the first time a short-term experiment it had conducted using a small amount of F598 antibodies, which Xenothera had procured from Brigham and Women's Hospital. Xenothera proposed that Xenothera and Alopexx launch a comparative trial pitting Alopexx's F598 and Xenothera's XAB05 directly against one another.

45. While Alopexx was willing to consider a potential license of AV0328 to Xenothera, if the parties could come to mutually beneficial terms, Xenothera had not previously indicated that it planned to use a license of AV0328 to develop a competitor product to F598. Alopexx wanted to ensure that Xenothera's XAB05, which is a polyclonal antibody, would not compete with Alopexx's F598 monoclonal antibody. To that end, Alopexx asked Xenothera to propose a particular indication or indications for XAB05 that would not compete with the planned development and use of F598

46. Xenothera did not propose any specific indications to Alopexx. Instead, Xenothera listed possible settings and types of physicians who might use XAB05.

47. Alopexx requested on more than one occasion that Xenothera propose a specifc non-overlapping indication for XAB05. Despite those requests, Xenothera never provided a term sheet, a proposal detailing the specific indication(s), financial terms, or any other specific proposal through which the parties could have come to any licensing agreement. The parties never entered into any substantive licensing discussions and did not come to any agreement.

E. Xenothera's 2022 Update to Alopexx

48. In March 2022, Xenothera contacted Alopexx again to provide an update on Xenothera's development activities.

49. During these discussions, Alopexx learned for the first time that, to develop XAB05, Xenothera had continued to conduct studies using antisera from the preliminary study relating to the AV0328 vaccine. These additional studies were aimed at developing a competitor to Alopexx's F598 product candidate and, thus plainly affected Alopexx's rights. Xenothera never sought Alopexx's consent to conduct the studies.

50. Alopexx also learned that Xenothera was recruiting financial investors based on representations about XAB05, including, on information and belief, suggesting that XAB05 is a commercially viable candidate product without disclosing that XAB05 would not exist without Alopexx's AV0328 vaccine and cannot be developed further without license rights from Alopexx to AV0328.

51. After learning about Xenothera's breaches, Alopexx demanded that Xenothera cease all studies involving material derived from use of the Alopexx vaccine and asked for additional information regarding Xenothera's past use of the AV0328 vaccine and related activities.

F. Xenothera's Baseless License Claim and Other Frivolous Claims

52. Xenothera did not provide the information requested by Alopexx about use of the AV0328 vaccine. Instead, even though Xenothera previously acknowledged that it had no right to continue to use Alopexx's AV0328 vaccine, Xenothera changed course. It claimed for the first time that it already had rights to a license to use the AV0328 vaccine, even though the MTA expressly and repeatedly disclaims any such license.

53. Xenothera's new license claim was made in a lawsuit against Alopexx filed in France in June 2022. Xenothera's lawsuit asserts entitlement to license the AV0328 vaccine or, in the alternative, payment of 120 million euros by Alopexx.

54. Xenothera's baseless claims came just as Alopexx began preparing its initial public offering. Alopexx's value is based largely on the value of its intellectual property and its plans for product development. By falsely claiming that it has a legal right to use Alopexx's proprietary vaccine, Xenothera has harmed Alopexx by casting a cloud of uncertainty over Alopexx's control of its valuable intellectual property.

55. In addition, Xenothera has suggested that its XAB05 product candidate is a viable competitor to Alopexx's F598 product candidate. In fact, however, XAB05 cannot compete with F598 because XAB05's future is dependent on Xenothera securing a legal right to use Alopexx's proprietary vaccine, which Xenothera does not have. Xenothera's false claims have harmed and will continue to harm Alopexx.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
(Declaratory Relief)

56. Alopexx re-alleges and incorporates by reference into this cause of action each and every allegation set forth in Paragraphs 1 through 56.

57. The Declaratory Judgment Act, 28 U.S.C. § 2201(a), provides that in "a case of actual controversy within its jurisdiction . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought."

58. An actual controversy has arisen between Alopexx and Xenothera as to the rights, duties, responsibility, and obligations of the parties in that Alopexx contends and, on information and belief, Xenothera disputes and denies that Xenothera lacks any ownership right or title, or option or license whatsoever over the AV0328 vaccine.

59. In May 2018, Alopexx and Xenothera had capacity to and did mutually enter into a written contract known as the MTA.

60. The MTA provides that "[t]he Parties hereby expressly agree that the right to use the MATERIAL, as granted under this Agreement, may not, under any circumstances, be construed as expressly or implicitly providing XENOTHERA with any ownership right or title, or option or license, whatsoever, over the MATERIAL or any ALOPEXX CONFIDENTIAL INFORMATION." MTA ¶ 4.2.

61. The MTA further provides that "No license shall be implicitly granted as a result of ALOPEXX providing the MATERIAL to XENOTHERA." MTA ¶ 5.3.

62. The MTA also provides that "MATERIAL" means "AV0328 held by ALOPEXX and whose transfer is the subject of this Agreement."

63. Alopexx seeks a declaratory judgment to affirm that Xenothera is entitled to no ownership right or title, or option, or license, whatsoever, over the AV0328 vaccine.

SECOND CAUSE OF ACTION
(Breach of Contract)

64. Alopexx re-alleges and incorporates by reference into this cause of action each and every allegation set forth in Paragraphs 1 through 64.

65. In May 2018, Alopexx and Xenothera had capacity to and did mutually enter into a written contract known as the MTA.

66. The MTA provides for ample valid consideration for Xenothera's contractual obligations to Alopexx pursuant to the MTA.

67. Alopexx has fully complied with all terms and conditions of the MTA and has fully performed all of its contractual obligations under the MTA. All conditions precedent, to the extent any exist, have occurred.

68. Under the plain terms of the MTA, Xenothera was only permitted to use Alopexx's AV0328 vaccine for the limited purpose of immunizing three pigs and obtaining antibodies from those pigs. Any further research related to the AV0328 vaccine following that initial, limited study would require the consent and further agreement of Alopexx.

69. As stated in the MTA, "[a]ccording to the results obtained," Alopexx and Xenothera were to jointly "decide whether to go on with further immunizations of the same animals, or to launch a new trial." MTA ¶ 1.4.

70. The MTA further provides that, "XENOTHERA is not allowed to conduct operations or transformations that may affect the rights of ALOPEXX, without the prior written consent of ALOPEXX." MTA ¶ 4.3.

71. Notwithstanding these clear restrictions, Xenothera conducted research derived from the original pig study using AV0328 to create an antibody product candidate—XAB05—that would potentially compete with Alopexx's F598 monoclonal antibody.

72. Xenothera's study and development of a product candidate—using Alopexx's AV0328 vaccine—to compete with Alopexx's monoclonal antibody product candidate without Alopexx's consent was a breach of the MTA. These Xenothera operations were directly contrary to Alopexx's interests and obviously "may affect" Alopexx's rights.

73. Likewise, Xenothera's public assertions that it is entitled to license Alopexx's AV0328 vaccine are operations directly contrary to Alopexx's interests and obviously "may affect" Alopexx's rights, in breach of the MTA.

74. Xenothera's development of XAB05 without Alopexx's consent and in a manner designed to compete with Alopexx's F598 product candidate and Xenothera's assertions that it has a right to license Alopexx's AV0328 vaccine have caused and will continue to cause damages to Alopexx.

75. Alopexx's damages include, but are not limited to, diminished demand for Alopexx stock due to the cloud cast over Alopexx's rights by Xenothera's baseless license claims and the suggestion that Xenothera is producing XAB05 as a viable competitor product to Alopexx's F598. Alopexx's damages also include legal fees and costs incurred in connection with enforcing Alopexx's rights under the MTA and defending against Xenothera's baseless lawsuit in France.

THIRD CAUSE OF ACTION
(Breach of Implied Covenant of Good Faith and Fair Dealing)

76. Alopexx re-alleges and incorporates by reference into this cause of action each and every allegation set forth in Paragraphs 1 through 76.

77. In May 2018, Alopexx and Xenothera had capacity to and did mutually enter into a written contract known as the MTA.

78. The MTA prohibited Xenothera from using the vaccine after one year or from using it for any purpose not expressly set out in the Agreement without Alopexx's written consent.

79. The MTA also prohibited Xenothera from conducting any operations that may affect the rights of Alopexx without Alopexx's consent.

80. After entering into the MTA, and in direct contravention of the terms and spirit of the agreement, Xenothera began using antisera induced by AV0328 to conduct further studies and to develop XAB05 to compete with Alopexx's F598, all without the prior written consent of Alopexx.

81. By using Alopexx's proprietary AV0328 vaccine and related confidential information to develop a product that is intended to directly compete with Alopexx's product monoclonal antibody F598, Xenothera has prevented Alopexx from receiving the benefit of the MTA.

82. Alopexx's damages include, but are not limited to, diminished demand for Alopexx stock due to the cloud cast over Alopexx's rights by Xenothera's baseless license claims and the suggestion that Xenothera is producing XAB05 as a viable competitor product to Alopexx's F598. Alopexx's damages also include legal fees and costs incurred in connection with enforcing Alopexx's rights under the MTA and defending against Xenothera's baseless lawsuit in France.

FOURTH CAUSE OF ACTION
(Unjust Enrichment)

83. Alopexx re-alleges and incorporates by reference into this cause of action each and every allegation set forth in Paragraphs 1 through 83.

84. In 2018, Alopexx provided to Xenothera with its proprietary AV0328 vaccine for the limited purpose of immunizing three animals with the vaccine. Xenothera paid nothing for use of Alopexx's valuable and proprietary vaccine technology.

85. Xenothera has used and benefitted from Alopexx's AV0328 vaccine and confidential information to develop a product that it intends to directly compete with Alopexx's monoclonal antibody F598.

86. Upon information and belief, Xenothera also used Alopexx's confidential information to seek necessary regulatory approvals to proceed with clinical testing in humans. All such use and benefit is outside of the terms of, and expressly prohibited by, the MTA under which Alopexx's AV0328 vaccine and confidential information was provided.

87. On information and belief, Xenothera has profited from its unauthorized use of Alopexx's AV0328 by raising funds related to study and development of XAB05, a candidate product developed through use of AV0328, without crediting or compensating Alopexx.

88. Alopexx expended considerable resources in terms of time and capital to develop the AV0328 vaccine and its confidential information.

89. Xenothera had full knowledge and appreciation of the benefits that it would achieve through misusing Alopexx's AV0328 vaccine and confidential information.

90. Allowing Xenothera to retain the benefit accrued through its improper use of Alopexx's AV0328 vaccine and confidential information would be inequitable absent payment for the value of the product and the information to Alopexx, particularly given that Xenothera has developed a directly competing product as a result of its improper use.

91. By using Alopexx's AV0328 vaccine and confidential information in its own work, Xenothera has bypassed a significant investment of time and capital to develop its own anti-microbial vaccine or to otherwise develop XAB05 without use of AV0328.

92. Alopexx is entitled to payment from Xenothera for the value of Xenothera's use of Alopexx's AV0328 vaccine and confidential information.

REQUESTED RELIEF

WHEREFORE, Alopexx requests that judgment be entered against Xenothera on each Count and that Alopexx be awarded the following relief:

1. A declaration that Xenothera is entitled to no ownership right or title, or option, or license, whatsoever, over the AV0328 vaccine;
2. Compensatory damages in an amount to be determined at trial;
3. Plaintiff's pre-judgment and post-judgment interest;
4. Attorneys' fees, costs, and any and all other expenses incurred in this action; and
5. Any such other relief as this Court deems just and proper.

Respectfully submitted,

Date: July 6, 2022

/s Michael M. Maya
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*Motions for admission *pro hac vice* forthcoming

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